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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,083	08/22/2001	Yixin Wang	P 280651 A0000364	7368
909	7590	10/02/2003	EXAMINER	
PILLSBURY WINTHROP, LLP P.O. BOX 10500 MCLEAN, VA 22102			LY, CHEYNE D	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/934,083		WANG ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Cheyne D Ly		1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                     | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                            | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1/02</u> . | 6) <input type="checkbox"/> Other: _____.                                   |

**DETAILED ACTION**

1. Claims 1-17 are examined on the merits.

**CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH**

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Specific to claim 15, line 5, the term “noise” causes the claim to be vague and indefinite because it is unclear what criteria are being used to determine specific signals as “noise” (audio or visual). Clarification of the metes and bounds of the instant claim is required.

5. Specific to claim 16, lines 5-6, the phrase “uninformative probes” causes the claim to be vague and indefinite because it is unclear what criteria are being used to consider that a probe is “uninformative” (lack of signal or false signal due to non-specific hybridization). Clarification of the metes and bounds of the instant claim is required.

6. Specific to claim 16, line 6, the phrase “one cut-off threshold” causes the claim to be vague and indefinite because it is unclear what criteria are being used to determine “one cut-off threshold” (a numerical value or a piece of wood or stone placed beneath a door). Clarification of the metes and bounds of the instant claim is required.

**CLAIM REJECTIONS - 35 USC § 101**

7. 35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory algorithm type subject matter.
9. Claims 1-11 are rejected because said claim is directed to a system comprising a DNA chip expression data wherein the descriptive material within the system is considered to be either functional, a system and computer readable media; or non-functional, DNA chip expression data, which are regarded as non-statutory subject matter. The MPEP indicates that descriptive material that cannot exhibit any functional interrelationship with the way in which computing processes are performed does not constitute a statutory process, machine, manufacture or composition (MPEP § 2106 (IV)(B)(1) (b)). Specific to the instant case, a system merely stores DNA chip expression data so as to be read without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer (MPEP § 2106 (IV)(B)(2) (a)).
10. Claims 1-11 are rejected due to the claimed subject matter being directed to a non-statutory subject matter due to lacking any means for displaying the stored information. Currently, the components of said system are merely algorithmic processes of manipulating data directed to DNA chip expression data without providing a means of visualizing the results of the said processes; therefore, the claim subject matter lacks a real world value. The claimed invention as a whole is directed to a combination of interrelated elements, which combine to form a machine for storing DNA chip expression data in a system without providing a means for displaying the stored DNA chip expression data. The critical steps of displaying the drug

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information would cause the subject matter in its entirety to be a practical application (MPEP § 2106 (IV)(B)(2) (b)).

**CLAIM REJECTION - 35 USC § 102**

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-15 and 17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Schena et al. (1996).

3. Schena et al. discloses a system and method for predicting splicing transcripts using DNA chip expression data (EST) wherein differential expression data (profiling) are derived from microarrays containing human cDNAs (EST) and analyzed using IMAGE software; EST data is accessed via the World Wide Web (network interface) from NCBI (GenBank), as in instant claims 1-6 and 9-11.

4. The inclusion of a document by Schuler (Schuler 1997) is not used as prior art but only to expand on the disclosure of the use of EST for predicting alternative splicing transcripts. As directed to human ESTs, some clones are derived from partially splice pre-mRNAs, which are nearly indistinguishable from true splicing variants (page 695, column 3, lines 32-36).

5. The inclusion of a document by Benson et al. (Benson et al. 1997) is not used as prior art but only to expand on the disclosure of GenBank as host server accessed via a network interface. GenBank is accessible via the World Wide Web, FTP, and e-mail server (Abstract etc.). Via the

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client server version of *Entrez*, client programs can access over the Internet the NCBI server (host) (page 5, column 1, lines 13-29).

6. Schena et al. disclose the advantages of using high capacity approaches to expression analysis via cDNA clones and oligonucleotide arrays (page 10618, column 2, lines 54-61 to page 10619, column 1, line 1) wherein control probes are used (page 10614, column 2, Microarray Preparation §) and treatment sets of cell-derived samples (page 10615, column 1, Cell Culture §), as in instant claims 7 and 8.

7. Test sample preparation is performed with tissues wherein mRNA is extracted, purified and quantified; and hybridization and scanning are performed for data processing (page 10614, column 2), as in claims 12-14.

8. Hybridization signals were observed to >95% of the human cDNA array elements, but not for any of the negative controls (page 10615, column 2, lines 6-8 and Figure 1). Each of the tissues samples was normalized to the control to generate an expression profile for each of the 1046 clones present on the array (page 10617, column 2, lines 6-10). Database searches revealed perfect matches for five of the six sequences (page 10617, column 1, lines 20-23). Table 1 contains data as directed to the normalized difference of the two ratios wherein said ratios are greater than half the average ratio (page 10616, Figure 2 and Table 1), as in instant claims 15 and 17.

### **CLAIM REJECTIONS - 35 USC § 103**

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schena et al. (1996) taken with Eisen et al. (1998).

13. Schena et al. discloses the limitations to claims 1-15 and 17 as discussed above.

14. However, Schena et al. (1996) does not disclose the step of generating f log ratio as directed to cDNA expression data.

15. Eisen et al. discloses a method for analyzing cDNA expression data wherein said method comprises a step for generating the log ratio of fluorescence ratio (page 14864, column 2, Display §), as in instant claim 16.

16. Schena et al. (1996) et al. discloses an improvement of using high capacity approaches to expression analysis via cDNA clones and oligonucleotide arrays (page 10618, column 2, lines 38-61 to page 10619, column 1, line 1) which is directly applicable to the method analyzing cDNA expression data generated from microarrays (Abstract etc.) as taught by Eisen et al.

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17. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated to partake the improvements disclosed by Schena et al. and practice the method of analyzing cDNA expression data wherein said method comprises a step for generating the log ratio of fluorescence ratio as taught by Eisen et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to practice the method of analyzing cDNA expression data wherein said method comprises a step for generating the log ratio of fluorescence ratio as taught by Schena et al. and Eisen et al.

### **CONCLUSION**

18. NO CLAIM IS ALLOWED.

19. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.




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22. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly  
9/29/03

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER